



KM/SMC

PLEASE STAMP TO ACKNOWLEDGE RECEIPT OF THE FOLLOWING:

In Re Application of: **Raymond G. GOODWIN et al.**

Application No.: 10/623,808

Group Art Unit: 1645

Examiner: Unassigned

Filed: July 22, 2003

Confirmation No. 5275

For: **MONOCLONAL ANTIBODIES THAT BIND HUMAN CELL SURFACE RECEPTOR 4-1BB (AS Amended)**



1. Preliminary Amendment and Response to Notice to File Missing Parts
2. Abstract
3. Copy of U.S. Patent No. 6,569,997
4. Copy of U.S. Patent Application Publication No. US 2003/0100745 A1
5. Statement to Support Filing and Submission of Sequence Listing
6. Request for Transfer of Form of Sequence Listing
7. Petition for One-Month Extension of Time
8. Check in the Amount of \$1,688.00 (filing fee of \$770, add'l claim fee of \$678, surcharge of \$130 and extension fee of \$110)

Dated: May 26, 2004

Docket No.: 03260.0148-01

Due Date: June 2, 2004

KJMEYERS/SMLEE/doh - Mail Drop 812

DAT-86-5/27/04



PATENT
Customer No. 22,852
Attorney Docket No. 3260.0148-01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Raymond G. GOODWIN et al.

Application No.: 10/623,808

Filed: July 22, 2003

For: MONOCLONAL ANTIBODIES
THAT BIND HUMAN CELL
SURFACE RECEPTOR 4-1BB (As
amended herein)

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) Group Art Unit: 1645
)
) Examiner: Unassigned
)
) Confirmation No. 5275
)
)
)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

**PRELIMINARY AMENDMENT AND
RESPONSE TO NOTICE TO FILE MISSING PARTS**

Prior to the examination of the above application, please amend this application
as follows:

Amendments to the Specification appear at page 2.

Amendments to the Claims appear at pages 3-7.

Remarks/Arguments begin at page 8.

Attachments to this Amendment include: Copies of US 6,569,997 B1 and US
2003/0100745 A1, and a replacement Abstract.

AMENDMENTS TO THE SPECIFICATION:

Please amend the specification as follows:

Please delete the Title and replace it with the following new Title:

-- MONOCLONAL ANTIBODIES THAT BIND HUMAN CELL SURFACE
RECEPTOR 4-1BB--

Please delete the Abstract and replace it with the new Abstract attached hereto
on a separate sheet.

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions and listings of claims in the application:

Claims 1-47 (Cancelled).

Claim 48 (New): An isolated monoclonal antibody that binds to a human cell surface receptor 4-1BB polypeptide consisting of SEQ ID NO:8, wherein the monoclonal antibody binds to endogenous human 4-1BB cell surface receptor on activated primary T-cells, the alloreactive CD4⁺ T-cell clone PL-1, EBV transformed B cell lines, the pro-monocytic cell line U937, and resting and activated peripheral blood monocytes.

Claim 49 (New): The monoclonal antibody according to claim 48, which is an IgG1 isotype.

Claim 50 (New): The monoclonal antibody according to claim 48, which has been raised against human 4-1BB/F_c fusion protein.

Claim 51 (New): The monoclonal antibody according to claim 50, wherein the human cell surface receptor 4-1BB polypeptide consists of amino acids 1-163 of SEQ ID NO:8.

Claim 52 (New): The monoclonal antibody according to claim 48, which is an antagonistic monoclonal antibody.

Claim 53 (New): The monoclonal antibody according to claim 48, which is an agonistic monoclonal antibody.

Claim 54 (New): The monoclonal antibody according to claim 51, which is an antagonistic monoclonal antibody.

Claim 55 (New): The monoclonal antibody according to claim 51, which is an agonistic monoclonal antibody.

Claim 56 (New): An isolated monoclonal antibody that binds to a human cell surface receptor 4-1BB polypeptide consisting of SEQ ID NO:8, wherein the monoclonal antibody binds to endogenous human 4-1BB cell surface receptor on activated primary T-cells.

Claim 57 (New): An isolated monoclonal antibody that binds to a human cell surface receptor 4-1BB polypeptide consisting of SEQ ID NO:8, wherein the monoclonal antibody binds to endogenous human 4-1BB cell surface receptor on the alloreactive CD4⁺ T-cell clone PL-1.

Claim 58 (New): An isolated monoclonal antibody that binds to a human cell surface receptor 4-1BB polypeptide consisting of SEQ ID NO:8, wherein the monoclonal antibody binds to endogenous human 4-1BB cell surface receptor on EBV transformed B cell lines.

Claim 59 (New): An isolated monoclonal antibody that binds to a human cell surface receptor 4-1BB polypeptide consisting of SEQ ID NO:8, wherein the monoclonal antibody binds to endogenous human 4-1BB cell surface receptor on the pro-monocytic cell line U937.

Claim 60 (New): An isolated monoclonal antibody that binds to a human cell surface receptor 4-1BB polypeptide consisting of SEQ ID NO:8, wherein the monoclonal antibody binds to endogenous human 4-1BB cell surface receptor on resting and activated peripheral blood monocytes.

Claim 61 (New): A hybridoma capable of producing the monoclonal antibody of claim 48.

Claim 62 (New): A hybridoma capable of producing the monoclonal antibody of claim 51.

Claim 63 (New): A hybridoma capable of producing the monoclonal antibody of claim 52.

Claim 64 (New): A hybridoma capable of producing the monoclonal antibody of claim 53.

Claim 65 (New): A hybridoma capable of producing the monoclonal antibody of claim 54.

Claim 66 (New): A hybridoma capable of producing the monoclonal antibody of claim 55.

Claim 67 (New): An isolated agonistic monoclonal antibody, which binds to human 4-1BB (H4-1BB) having SEQ ID NO:8.

Claim 68 (New): An isolated antagonistic monoclonal antibody, which binds to human 4-1BB (H4-1BB) having SEQ ID NO:8.

Claim 69 (New): The antibody of claim 67, which binds to T cells.

Claim 70 (New): The antibody of claim 68, which binds to T cells.

Claim 71 (New): The antibody of claim 67, which is of the IgG isotype.

Claim 72 (New): The antibody of claim 68, which is of the IgG isotype.

Claim 73 (New): A hybridoma capable of producing the antibody of claim 67.

Claim 74 (New): A hybridoma capable of producing the antibody of claim 68.

Claim 75 (New): A monoclonal antibody against 4-1BB which specifically recognizes an epitope on the extracellular domain of receptor protein 4-1BB.

Claim 76 (New): A hybridoma capable of producing the monoclonal antibody of claim 70.

REMARKS

In response to the Notice to File Missing Parts mailed March 2, 2004, the period for response having been extended to June 2, 2004, by a request for extension of one (1) month and fee payment filed concurrently herewith, Applicants submit herewith (1) the statutory basic filing fee of \$770, the late filing fee surcharge of \$130, and an additional claim fee of \$678, calculated based on the claim amendments made herein; (2) a Request for Transfer of Form Under 37 C.F.R. § 1.821(e), requesting that the computer readable copy of the Sequence Listing on file in Parent Application No. 09/151,259 be used in the instant application; and (3) a Statement to Support Filing and Submission in Accordance with 37 C.F.R. §§ 1.821-1.825, stating that, on information and belief, the paper copy of Sequence Listing filed July 22, 2003, and the computer readable form of the Sequence Listing that was filed in parent application No. 09/151,259, filed September 10, 1998, are identical, and do not add new matter.

A. Preliminary Amendment

The listing of claims filed herewith cancels claims 1-47 without prejudice to or disclaimer of the subject matter recited therein, and adds new claims 48-76. Claims 48-76 are pending in the application.

New claims 67-74 have been copied from United States Patent No. 6,569,997 B1 (the "'997 patent"), a copy of which is attached hereto for the Examiner's convenience.¹ The '997 patent issued on May 27, 2003. Accordingly, applicants have filed claims

1. Applicants note that claims 67-74 refer to SEQ ID NO:8, while the claims of the '997 patent refer to SEQ ID NO:2. In each case, these sequence identification numbers refer to the human 4-1BB protein.

67-74 within the one year time period prescribed by 35 U.S.C. § 135(b)(1). Applicants are currently reviewing their specification and the '997 patent for possible interference.

New claims 75 and 76 have been copied from United States Patent Application Publication No. US 2003/0100745 A1 (the "'745 application"), a copy of which is attached hereto for the Examiner's convenience. The '745 application published on May 29, 2003. Accordingly, applicants have filed claims 75 and 76 within the one year time period prescribed by 35 U.S.C. § 135(b)(2). Applicants are currently reviewing their specification and the '745 application for possible interference.

New claims 48-66 have not been copied directly from either the '997 patent or '745 application. However, the Office may conclude that some or all of claims 48-66 may interfere with at least one claim of the '997 patent and/or '745 application.

New claims 48-76 find support throughout the application, such as at the locations indicated in the following table.

Claim	Example of Support in Application
48	Page 32, line 36 – page 33, line 3; page 34, lines 26-34.
49	Page 34, lines 28-30.
50	Page 25, lines 13-15; page 26, lines 3-9; page 6, lines 1-5.
51	Page 4, lines 23-28; page 5, lines 10-13; page 6, lines 1-5.
52	Page 34, lines 26-34.
53	Page 34, lines 26-34.
54	Page 4, lines 23-28; page 5, lines 10-13; page 6, lines 1-5.

Claim	Example of Support in Application
55	Page 4, lines 23-28; page 5, lines 10-13; page 6, lines 1-5.
56	Page 34, lines 26-34.
57	Page 34, lines 26-34.
58	Page 34, lines 26-34.
59	Page 34, lines 26-34.
60	Page 34, lines 26-34.
61	Page 32, line 10 – page 23, line 1.
62	Page 32, line 10 – page 23, line 1.
63	Page 32, line 10 – page 23, line 1.
64	Page 32, line 10 – page 23, line 1.
65	Page 32, line 10 – page 23, line 1.
66	Page 32, line 10 – page 23, line 1.
67	Page 32, line 36 – page 33, line 3; page 34, lines 26-34.
68	Page 32, line 36 – page 33, line 3; page 34, lines 26-34.
69	Page 34, lines 30-34.
70	Page 34, lines 30-34.
71	Page 34, lines 26-30.
72	Page 34, lines 26-30.
73	Page 32, line 10 – page 23, line 1.
74	Page 32, line 10 – page 23, line 1.
75	Page 25, line 11 – page 26, line 9; page 32, line 36 – page 33, line 3.

Claim	Example of Support in Application
76	Page 32, line 10 – page 23, line 1.

Applicants have amended the Title and Abstract to be more descriptive of the general subject matter of the new claims. Neither the Title nor the Abstract are intended to limit applicants' invention.

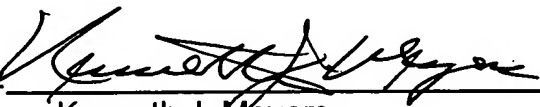
Applicants courteously request entry of this Preliminary Amendment prior to examination of this application.

If there is any fee due in connection with the filing of this Preliminary Amendment, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: May 26, 2004

By: 
Kenneth J. Meyers
Reg. No. 25,146

Attachments: US 6,569,997 B1
US 2003/0100745 A1
New Abstract

ABSTRACT

Monoclonal antibodies that bind to a human cell surface receptor 4-1BB polypeptide are provided. The human cell surface receptor 4-1BB polypeptide may consist of amino acids 1-163 of SEQ ID NO:8. The monoclonal antibody may be isolated, of IgG1 isotype, and/or raised against human 4-1BB/F_c fusion protein. The monoclonal antibody may be antagonistic or agonistic. The monoclonal antibody may bind to endogenous human 4-1BB cell surface receptor on activated primary T-cells, the alloreactive CD4⁺ T-cell clone PL-1, EBV transformed B cell lines, the pro-monocytic cell line U937, and/or resting and activated peripheral blood monocytes. The monoclonal antibody may specifically recognize an epitope on the extracellular domain of receptor protein 4-1BB. Also provided are hybridomas capable of producing the monoclonal antibodies of the invention.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
)	
Raymond G. GOODWIN et al.)	
)	
Application No.: 10/623,808)	Group Art Unit: 1645
)	
Filed: July 22, 2003)	Examiner: Unassigned
)	
For: MONOCLONAL ANTIBODIES THAT)	
BIND HUMAN CELL SURFACE)	Confirmation No. 5275
RECEPTOR 4-1BB (<i>As amended</i>))	

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

STATEMENT TO SUPPORT FILING AND SUBMISSION
IN ACCORDANCE WITH 37 C.F.R. §§ 1.821-1.825

In connection with the Sequence Listing submitted July 22, 2003, and the Request for Transfer of Form Under 37 C.F.R. § 1.821(e) submitted herewith, the undersigned hereby states that:

1. On information and belief, the submission, filed herewith in accordance with 37 C.F.R. § 1.821(g), does not include new matter;
2. On information and belief, the content of the paper copy of Sequence Listing filed July 22, 2003, and the computer readable form of the Sequence Listing that was filed in parent application No. 09/151,259, filed September 10, 1998, are identical;
and


3. All statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent resulting therefrom.

If any fees are necessary for the submission of the sequence listing, please charge our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: May 26, 2004

By: 
Kenneth J. Meyers
Reg. No. 25,146

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
)	
Raymond G. GOODWIN et al.)	Prior Group Art Unit: 1645
)	
Application No.: 10/623,808)	Prior Examiner: Unassigned
)	
Filed: July 22, 2003)	Confirmation No. 5275
)	
For: MONOCLONAL ANTIBODIES)	
THAT BIND HUMAN CELL)	
SURFACE RECEPTOR 4-1BB (As)	
amended))	

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

REQUEST FOR TRANSFER OF FORM
UNDER 37 C.F.R. § 1.821(e)

On information and belief, the paper copy of the Sequence Listing in this application, filed together with the application on July 22, 2003, is identical to the computer readable copy of the Sequence Listing on file in parent Application No. 09/151,259, filed September 10, 1998. In accordance with 37 C.F.R. § 1.821(e), please use the computer readable form on file in that application as the computer readable form for the instant application.

It is understood that the United States Patent and Trademark Office will make the necessary change in application number and filing date for the instant application.

If there is any fee due in connection with the filing of this Request, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: May 26, 2004

By: 

Kenneth J. Meyers
Reg. No. 25,146



PATENT
Customer No. 22,852
Attorney Docket No. 3260.0148-01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Raymond G. GOODWIN et al.

Application No.: 10/623,808

Filed: July 22, 2003

For: MONOCLONAL ANTIBODIES
THAT BIND HUMAN CELL
SURFACE RECEPTOR 4-1BB (As
amended)

)
)
) Group Art Unit: 1645

)
) Examiner: Unassigned

)
)
) Confirmation No.: 5275

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

PETITION FOR EXTENSION OF TIME

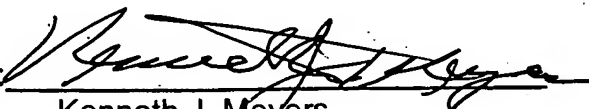
Applicants hereby petition for a one month extension of time to reply to the Office
Action of March 2, 2004. A fee of \$110.00 is enclosed.

Please grant any extensions of time required to enter this response and charge
any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: May 26, 2004

By: 
Kenneth J. Meyers
Reg. No. 25,146

FINNEGAN, HENDERSON, FARABOW
GARRETT & DUNNER, L.L.P.

1300 I Street, N.W.
Washington, D.C. 20005-3315

CRESTAR BANK N.A.
WASHINGTON, D.C. 20005

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OF

COMMISSIONER OF PATENTS AND TRADEMARKS

Christopher P. Foley

VOID AFTER 180 DAYS

⑈00086611⑈ ⑆05400052⑆ 206744587⑈

DETACH AND RETAIN THIS STATEMENT
THE ATTACHED CHECKS IS IN PAYMENT OF ITEMS DESCRIBED BELOW.
IF NOT CORRECT PLEASE NOTIFY US PROMPTLY. NO RECEIPT DESIRED.

FINNEGAN, HENDERSON, FARABOW
GARRETT & DUNNER, L.L.P.

086611

VENDOR I.D.#/GL#	INVOICE DATE	INVOICE #	INVOICE AMOUNT
03260 0148-01000	05/25/04	311373	770.00
03260 0148-01000	05/25/04	311373	110.00
03260 0148-01000	05/25/04	311373	678.00
03260 0148-01000	05/25/04	311373	130.00
Beckford-Harris MD 812			1,688.00

